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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,098	09/20/2001	Yukio Toyoda	46342/56000	9857

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EXAMINER	
MITCHELL, LAURA MCGILLEM	
ART UNIT	**PAPER NUMBER**
1636	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/869,098	TOYODA ET AL.	
	Examiner	Art Unit	
	Laura M. Mitchell	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8, 11 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,11 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

It is noted that claims 1-7, 9-10 and 12-16 are cancelled in the amendment filed 10/15/2007. Claims 8, 11 and 17 are under examination. It is noted that in Office Action mailed 8/8/2007 claims 8, 11 and 17 were indicated as allowable, however on further consideration, new grounds of rejection are applied below.

Specification

The substitute specification filed 10/15/2007 has been entered. The statement of no new matter is provided in REMARKS page 6. Both marked and unmarked copies of the substitute specification have been provided in the filing of 10/15/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 5-7 have been canceled, therefore their rejection as being anticipated by Surwit et al (WO 98/31396, 7/23/1998) is mooted.

Claim 8 is rejected under 35 U.S.C. 102(a) as being anticipated by Surwit et al (WO 98/31396, 7/23/1998).

Surwit was previously applied as prior art that teaches a recombinant vector comprising a human UCP-2 promoter sequence. Although the method of claim 8 does not specifically use the word vector or plasmid, it does recite a UCP2 promoter sequence wherein the promoter sequence consists of all or a part of a base sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1, wherein the part of the base sequence consists of nucleotides 255 to 430 of SEQ ID NO: 1, nucleotides 255 to 717 of SEQ ID NO: 1, nucleotides 717 to 1133 of SEQ ID NO:1, nucleotides 1133 to 1389 of SEQ ID NO: 1, nucleotides 255 to 1857 of SEQ ID NO: 1, nucleotides 571 to 2270 of SEQ ID NO: 1, nucleotides 717 to 2270 of SEQ ID NO: 1, nucleotides 1133 to 2270 of SEQ ID NO: 1, nucleotides 1389 to 2270 of SEQ ID NO: 1, or nucleotides 1634 to 2270 of SEQ ID NO:

Surwit et al teach the identification and cloning of nucleic acid sequences encoding hUCP-2 and 5' sequences controlling the expression of hUCP-2. Surwit et al specifically disclose that the fragment contains the putative promoter region (see page 16, lines 1-20). Further, Surwit et al teach the isolation of a lambda EMBL3 phage comprising ~14 kb of human sequences. This clone comprises all 8 exons of the human UCP-2 gene, as well as a minimum of 3 kb of DNA upstream of the putative +1 site (see page 32, lines 23-28 bridging to page 33, lines 1-5, in particular). Given the size of the genomic clones obtained by the inventors of the Surwit et al application (e.g. at least 3 kb upstream of the transcription initiation site) and the fact that the sequences recited in the claims are all within ~2.2 kb of the initiation site (e.g. see amended Figure 4 of the instant Specification), absent evidence to the contrary the clones obtained by Surwit et

al necessarily comprise SEQ ID NO: 1 and the recited parts thereof. Therefore Surwit et al anticipate a human UCP-2 promoter sequence wherein the sequence consists of all or a part of a base sequence consisting of nucleotides 1 to 2270 or a part of the base sequence as recited in claim 8.

Surwit et al teach methods of screening compounds for the ability to modulate the activity or expression of UCP2 (see page 18, lines 23-28 bridging to page 19, lines 1- 10, in particular). Surwit et al teach constructs comprising a UCP2 promoter operably linked to a reporter gene which are introduced into host cells (see page 19, lines 12-23 and page 13, for example), which meets the limitation of a base sequence encoding a reporter molecule inserted downstream of the human UCP2 promoter in a transformant.

Surwit et al teach embodiments of the screening method wherein the expression of the reporter gene is examined in the presence and absence of the test compound (see page 19, lines 14-19, for example). Surwit et al disclose vectors comprising promoters other than the UCP2 promoter ,such as CMV promoters, SV40 promoter and MMTV promoters (see page 14, lines 1-13, for example) which meets the limitation of a base sequence encoding a reporter molecule but with no UCP-2 promoter. Surwit et al teach constructs comprising promoters operably linked to reporter genes which are introduced into host cells (see page 19, lines 12-23 and page 13, for example). It would be obvious to the skilled artisan to include a control vector comprising a sequence encoding the reporter molecule without the promoter being examined (i.e. without a UCP-2 promoter) in the promoter activity screening assay. Therefore, Surwit et al anticipate a method for screening a compound or its salt for inhibition or promotion of

human UCP-2 promoter activity comprising contacting a transformant comprising a human UCP-2 promoter sequence, wherein the human UCP-2 promoter sequence consists of all or a part of a base sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1 or parts thereof and a base sequence encoding the reporter molecule inserted downstream of the human UCP-2 promoter and contacting a control transformant with a base sequence encoding the reporter molecule but with no human UCP-2 promoter with the compound or its salt and measuring the expression level of a reporter molecule comparing the expression levels thereof (**claim 8**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit et al (WO 98/31396, 7/23/1998) in view of the Stratagene catalog (1988 Table of contents, page 39).

Applicants claim a kit for screening for a compound or its salt that promotes or inhibits a human UCP-2 promoter activity, which comprises a medium for culturing a host animal cell line, a plasmid for measurement of the human UCP-2 promoter activity, which comprise a human UCP-2 promoter sequence consisting of all or a part of a base sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1, wherein the part of the

base sequence consists of nucleotides 255 to 430 of SEQ ID NO: 1, nucleotides 255 to 717 of SEQ [I3 NO: 1, nucleotides 717 to 1133 of SEQ ID NO: 1, nucleotides 1133 to 1389 of SEQ ID NO: 1, nucleotides 255 to 1857 of SEQ ID NO: 1, nucleotides 571 to 2270 of SEQ ID NO: 1, nucleotides 717 to 2270 of SEQ ID NO: 1, nucleotides 1133 to 2270 of SEQ ID NO: 1, nucleotides 1389 to 2270 of SEQ ID NO: 1, or nucleotides 1634 to 2270 of SEQ ID NO: 1; and a base sequence encoding a reporter molecule inserted downstream of the human UCP-2 promoter; and a host animal cell line.

The teaching of Surwit et al has been detailed in the above rejection. Specifically Surwit et al teach plasmid clones comprising a human UCP-2 promoter sequence as claimed, operably linked to a sequence encoding a reporter protein. Surwit et al teach host animal cell lines for use in agent screening assays (see page 19, lines 17-24, for example). Surwit et al exemplify an assay in which an adipocyte cell line expressing UCP2 was cultured in a medium comprising an insulin sensitizing agent for seven days to determine the effect of the agent (see column 37, lines 22-28, for example) which meets the limitation of a medium for culturing a host animal cell line and a host animal cell line. It would be obvious to the skilled artisan to culture the host cell line in an appropriate medium to the host cell line being used to produce normal, healthy cell cultures. Surwit et al does not specifically teach that the plasmid as claimed comprising a human UCP2 promoter sequence linked to a sequence encoding a reporter molecule is combined with a host cell line and medium in a kit form.

The Stratagene 1988 catalog discloses the advantage of using gene characterization kits. Stratagene teach that the advantage of a kit is that the variety of

different reagents are assembled and premixed specifically for a defined set of experiments, and that components of a kit are subject to quality control (see page 39, left column, in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the elements taught by Surwit et al into a kit because Stratagene teaches that it is advantageous to have reagents in a kit format. The motivation to combine the plasmid, medium and host cell line in a kit is the expected benefit as taught by Stratagene of being able to reduce waste of reagents and money because it is not necessary to buy or make large quantities of different reagents to begin a series of experiments. There is a reasonable expectation of success in being able to combine the multiple elements for promoter activity assays into a kit since it has worked previously in the cited reference. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention. Therefore, Surwit et al in view of the Stratagene catalog 1988 page 39 render obvious a kit comprising the plasmid as claimed, a medium for culturing a cell line and a host animal cell line (**claim 11**).

Surwit et al teach that the UCP2 promoter can be operably linked to reporter genes such as luciferase and GFP (see page 19, lines 11-16, for example), which meets the limitation of a reporter gene that is luciferase (**claim 17**).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura M. Mitchell whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura M. Mitchell
Examiner
1/3/2008

CELINE QIAN, PH.D.
PRIMARY EXAMINER